DEC 2 2 2005

510(k) Number K052328 Date 12/22/05

ZAN Lung-Function Lab
510(k) Summary

Submitter

Company:	ZAN Messgeräte GmbH Schlimpfhofer Strasse 14, D-97723 Oberthulba, Germany Tel +49 97 36 81810, Fax +49 97 36 818120
Contact:	Jim Lewis Ferraris Respiratory Inc, 908 Main Street, Louisville CO 80027, USA Tel 303 666 5555, Fax 303 666 5588
Prepared:	August 2005

Device Name

Trade:	ZAN Lung-Function Lab
Common:	Pulmonary function test equipment
Classification:	Pulmonary-function data calculator, 21 CFR 868.1880; Class II
Product code:	73-BZC

Predicate Devices

Trade Name:	CPL Pulmonary Function Test System
510(k) Number:	K992743
Manufacturer:	Ferraris Respiratory, Inc.
Trade Name:	Vmax Series Diagnostic Instruments
510(k) Number:	K942211
Manufacturer:	SensorMedics, Inc.

Device Description

The ZAN Lung-Function Lab (LFL) is a full-featured, PC-based system for professional evaluation of pulmonary function, cardiopulmonary exercise capacity, and metabolism in any adult or pediatric subject able to understand the test instructions and execute the test maneuvers.

A personal computer (PC) is the central component of thi lung-function test, stress, and training system: collecting data from pulmonary-function and related test instruments, calculating pulmonary-function values from these inputs, correlating them with demographic and other subject information, and displaying/reporting the results.

The system comprises

- Four pulmonary instruments — flow sensor with airway pressure capability, diffusion-gas analyzer, ventilation-gas analyzer, and body plethysmograph
- A PC running a proprietary ZAN test program

- Test gases of known compositions, as needed
- Leads, tubes, and valves connecting the instruments to the subject and to each other
- An optional cart for holding the instruments, gases, and computer.

In addition, optional physiologic sensing equipment — including exercise electrocardiographs, pulse oximeters, blood pressure monitors, and pulse monitors — may supply data to the computer to provide expanded testing capability.

The LFL can meet the majority of lung-function testing needs: spirometry, pulmonary-function analysis, cardiopulmonary exercise testing, nutritional assessment, or combined pulmonary-function/cardiopulmonary-exercise testing applications.

Indications for Use

ZAN Lung-Function Lab may measure or monitor pulmonary function in adult and pediatric subjects during exercise (including diagnosis, training, and stress testing) or while at rest (including spirometry, airway strength and compliance, diffusion capacity, body plethysmography, nutritional assessment, and indirect cardiac output) for diagnosis, rehabilitation, performance enhancement, and other related activities.

Summary of Technological Characteristics

The LFL flow sensor measures gas flow rate using pneumotachometry (using differential pressure across a known flow restrictor). The flow path in the pneumotach is a reusable element mountable in pneumatic communication to the diffusion-gas module, the ventilation-gas module, or the plethysmograph. A shutter may be added to the unit to create a static head pressure for measuring airway pressures using the pressure sensor in the unit.

Diffusion capacity is calculated by inspiration and expiration of trace amounts of carbon monoxide (0.2% CO) and methane (0.3% CH_4) in a test gas using a standard single-breath method or by a CO rebreathing technique. Both trace gases are detected and measured using the common infrared absorption method.

Fast-gas (breath-by-breath) analysis techniques of ventilatory gases also use tried-and-true techniques. The three gases of interest in ventilation are oxygen (O_2), carbon dioxide (CO_2), and nitrogen (N_2). Two of these gases, O_2 and CO_2, are measured directly; N_2 is calculated knowing the concentrations of the other two gases. Oxygen concentration is measured by optical spectrometry. Carbon dioxide is measured by infrared absorption.

Body plethysmography indicates pulmonary parameters and capacities by measuring the pressure change in a "body box" (a sealed aluminum and glass enclosure) compared to flow and mouth pressures in a closed breathing circuit. This technique is well-known and standardized[1] in the industry.

[1] American Association for Respiratory Care. Clinical Practice Guideline: Body Plethysmography, 2001 Revision & Update. *Respir Care* 2001:46(5):506-513.

Technical Specifications

- Operating temperature range: 10 to 40 °C
- Operating humidity: 10 to 90%, non-condensing
- Storage temperature: 0 to 40 °C
- Storage humidity: 0 to 90%, non-condensing

System cart

- Dimensions: 80x55x130 cm
- Weight: 70 kg
- Features: Mains power supply and distribution with isolation transformer; shelves to hold modules, computer, mouse, and display
- Power In: 120 V, 60 Hz
- Power Out: One 12 VDC, 5 A max; one 24 VDC, 3 A max
- Enclosure rating: IPX0

Flow sense module

Flow sensor body

- Dimensions: 100x90x45 mm
- Weight: 250 g
- Flow sensing:
  - Pressure transducer: Semiconductor; 0 to 1.4 kPa; 0.1% accuracy
  - Volume resolution: <5 ml
  - Flow resolution: <1 ml/s
  - Flow sensor: FlowSensor Type 2a
- Mouth/Nasal pressure sensing:
  - Pressure transducer: Semiconductor; 0 to 7 kPa; 0.1% accuracy
- Type of applied part: BF (subject floating)
- Enclosure rating: IPX1
- Power supply: 12 VDC, 950 mA

FlowSensor Type 2a

- Material: POM (polyoxymethylene)
- Measuring principle: Pressure difference with variable diaphragm (pneumotachometry)
- Range:0 to 15 l/s, bi-directional
- Max linearity error (corrected): 2.5%
- Flow resistance: <0.03 kPa/l/s
- Effective dead space: <50 ml

Shutter valve for mouth/nasal pressure reading

- Dimensions: 140x55x50 mm
- Additional dead space: <30 ml
- Power supply: 12 VDC, 1.6 A

Diffusion-gas analyzer

Module

- Dimensions: 160x60x200 mm
- Weight: 250 g
- Case material: ABS
- Power: 12 VDC, 5 A max
- Enclosure rating: IPX0

CO analyzer

- Technology: Infrared absorption
- Measurement range: 0 to 3000 ppm
- Accuracy: <1%
- Neutral point drift: <2% per week
- Linearity: <1%

CH_4 analyzer

- Technology: Infrared absorption
- Measurement range: 0 to 3000 ppm
- Accuracy: 1%
- Neutral point drift: <2% per week
- Linearity: <1%

Test gas 0.2% CO, 0.3% CH_4, 99.5% synthetic air

Gas-exchange analyzer

Module

- Power: 24 VDC, 3 A max
- Enclosure rating: IPX0

O_2 analyzer

- Technology: Optical spectrometer
- Measurement range: 0 to 100%
- Accuracy: 0.1%
- Resolution: 0.1%
- Linearity: 0.2%

CO_2 analyzer

- Technology: Infrared absorption
- Measurement range: 0 to 10%
- Resolution: 0.1%
- Accuracy: 0.1%
- Linearity: 0.1%

Body Plethysmograph

- Power: 12 VDC, 5 A & 24 VDC, 3 A max
- Pressure transducer: Semiconductor; ±0.25 kPa;0.05% accuracy
- Case materials: Security glass and aluminum

Adult enclosure

- Dimensions: 71x87x174 cm
- Volume: 980 L
- Weight: 145 kg

Child enclosure

- Dimensions: 58x63x130 cm
- Volume: 380 L
- Weight: 85 kg

Summary of Non-Clinical Performance Data

Safety

Proprietary components of the LFL have been examined and bench tested by third-party examiners to demonstrate conformance to three recognized international consensus standards for safety of medical electrical equipment: EN 60601-1 for general medical-device safety, EN 60601-1-1 for medical electrical safety, and EN 60601-1-2 for electromagnetic compatibility.

Effectiveness

In-house and third-party testing demonstrate that the LFL measurement performance meets or exceeded published American Thoracic Society requirements and the claimed performance requirements under stated and anticipated operating conditions. Cardiopulmonary testing was performed in-house against a Douglas Bag (the classic standard measure) and competing units. Gas exchange was tested against a simulation system as well.

Summary of Clinical Performance Data

CE marking and years of successful operation in Europe demonstrate that patients and clinicians can safely and effectively use the LFL under actual-use conditions and that the users guide, product physical design, and other human-factor characteristics of the LFL system are appropriate for the product's intended use.

Equivalence to Predicate Devices

The LFL design uses similar technologies and design principles as its predicate devices. The system is substantially equivalent to the SensorMedics Vmax and the Collins CPL: using similar measurement principles, construction, material, and energy source; and meeting the same performance characteristics and intended uses. The LFL adds a few more calculated features, such as the Indirect Fick Principle for implied cardiac output, and reports a slightly different list of spirometric and predicted values than the Vmax and the CPL. However, these calculations and reports are recognized alternate forms and parameters for presenting pulmonary performance and do not represent any efficacy and safety issues or new claims or uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Zan Messgerate GMBH
C/O Mr. Jim Lewis
Ferraris Respiratory, Incorporated
908 Main Street
Louisville, Colorado 80027

Re: K052328
Trade/Device Name: ZAN LUNG-FUNCTION LAB
Regulation Number: 868.1880
Regulation Name: Pulmonary-Function Date Calculator
Regulatory Class: II
Product Code: BZC and BZG
Dated: December 1, 2005
Received: December 2, 2005

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

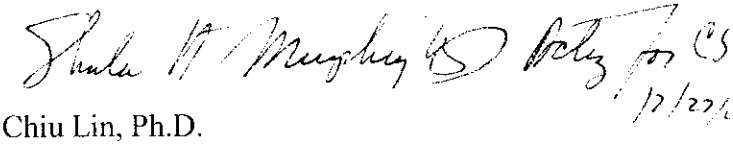
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052328

Device Name: ZAN Lung-Function Lab

Indications for Use:

ZAN Lung-Function Lab is used to measure or monitor pulmonary function in adult and pediatric subjects during exercise (including diagnosis, training, and stress testing) or while at rest (including spirometry, airway strength and compliance, diffusion capacity, body plethysmography, nutritional assessment, and indirect cardiac output) for diagnosis, rehabilitation, performance enhancement, and other related activities.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052328